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Feasibility and Effectiveness of a Pilot Health Promotion Program for Adults With Type 2 Diabetes:

Lessons Learned

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Abstract

Purpose—The purpose of this pilot study was to assess the feasibility and effectiveness of an intense health promotion program in older adults with diabetes. The program combined individually prescribed and supervised exercise with nutrition and education programs on glycemic control and aerobic fitness.

Methods—Various recruitment and retention strategies were analyzed for effectiveness. Out of 28 potential subjects assessed for eligibility, 6 subjects with type 2 diabetes (2 male and 4 female; all white; age, 60.2 ± 4.7 years) participated in the 10-week intervention. Aerobic and resistance exercise was performed on alternate days (3–4 days per week), with individualized nutrition counseling and diabetes health education sessions once weekly. The primary outcome measures were aerobic fitness and glycemic control (A1C), and secondary outcome measures included body mass index (BMI), self-efficacy, and symptoms of neuropathy. Changes in outcomes were assessed using descriptive statistics and paired *t* test analysis ($\alpha = .05$).

Results—Following the intervention, subjects had improvements that approached significance in A1C and pain, with significant improvements in self-efficacy.

Conclusions—A systematic approach to analysis of feasibility revealed issues with recruitment and retention that would need to be addressed for future studies or clinical implementation of this program. However, for the subset of subjects who did complete the intervention, adherence was excellent, and satisfaction with the program was confirmed by exit interview comments. Following participation in this pilot health promotion program, subjects had meaningful improvements in glycemic control, pain, and self-efficacy.

Lifestyle changes including healthy diet and exercise can significantly reduce the prevalence of diabetes and its complications.^{1,2} However, people with diabetes report limited participation in health promotion activities because of factors such as lack of knowledge, lack of coordinated care, feelings of helplessness, depression, lack of confidence, and feeling tired.^{3–5}

Several studies have demonstrated improved metabolic control following aerobic and strengthening exercise in people with diabetes or with impaired insulin resistance.^{6,7} Dietary

recommendations also are an important part of disease management for diabetes to reduce weight and improve glucose control.⁸ However, health promotion interventions that combine intense, supervised exercise with customized dietary information and education for people with diabetes are limited in the literature. Many exercise trials for people with diabetes do not incorporate individualized dietary counseling (eg, Sigal et al⁶), and many educational and dietary intervention trials do not incorporate supervised exercise (eg, Williamson et al⁹). The large Diabetes Prevention Program (DPP) trial did include diet, exercise, and behavioral modifications as part of the intensive lifestyle intervention group for subjects at risk for diabetes.² The outcomes for this intervention group, including a 16-lesson curriculum delivered over a 24-week period, were superior to the groups that received metformin or placebo control. However, the exercise intervention was not supervised and only included the recommendation of 150 minutes of brisk walking each week. These healthy subjects who did not have diabetes were able to increase their leisure physical activity levels, decrease weight, and improve glycemic control as a result of the intervention. However, subjects who have a diagnosis of diabetes, with the myriad of potential complications and disability associated with this disease, will likely need a more individualized and supervised exercise intervention. The “brisk walking” recommended in the DPP trial would be very difficult for subjects with pain or disability. In fact, it could be contraindicated in subjects with neuropathy or other diabetic complications. Consequently, studying the feasibility of including supervised, moderately intense exercise with other components of diabetic education to increase physical fitness and improve glycemic control is important.

The purpose of this pilot study was to assess the feasibility and effectiveness of an intense health promotion program in older adults with diabetes. A moderately intense, comprehensive health promotion program was implemented in adults with diabetes that included supervised and individualized aerobic and strength training, dietary counseling, and education. Our goals were to assess (1) the feasibility (including recruitment, retention, and adherence) and (2) the effect on glycemic control and aerobic fitness of this pilot program to develop our plans for implementing this intervention in a future large study.

Research Design and Methods

Research Design

During a 6-month period, our goal was to enroll 20 subjects in the 10-week health promotion intervention in a pretest-posttest single group design as a pilot study to assess feasibility and effectiveness in selected outcome measures. Pilot studies are an important first step with a new intervention to identify barriers and issues to address before implementing a large, randomized controlled trial.

Subjects

Subjects aged 40 to 70 years old who had been diagnosed with type 2 diabetes were enrolled in the study, after signing institutionally approved informed consent forms. All subjects were required to have documentation from their physician that they did not have any contraindications to maximal exercise testing. Subjects were excluded from the study if they presented with any of the following: (1) hospitalization for myocardial infarction, heart surgery, or congestive heart failure during the preceding 3 months; (2) significant cardiac arrhythmia, hypertrophic cardiomyopathy, severe aortic stenosis, or pulmonary embolus; (3) recent symptoms of chest discomfort; (4) currently smoking or significant pulmonary pathology; (5) serious musculoskeletal problems that would limit ability to exercise; (6) current active involvement in a regular exercise program (>3 times per week); (7) open wounds on the weightbearing surface of the feet; (8) inability to ambulate independently; (9)

stroke or other central nervous system pathology; or (10) stage 2 hypertension (resting blood pressure >160 mm Hg systolic or >100 mm Hg diastolic).

Subjects were recruited for this study through flyers posted in the community, distributed at health fairs, and via broadcast e-mail at the medical center. We attempted to specifically target uninsured or underinsured individuals by personally visiting 10 local safety net clinics to discuss the project with the office staff and left flyers in the waiting rooms of each. We also sent information to subjects who were known to us through previous studies.

Intervention

The Diabetes Health Promotion Program (DHPP) is a 10-week program that included education, exercise, and nutrition components (summarized in Table 1). This program was implemented with small cohorts of subjects to promote the development of a supportive network within the group members. The weekly time commitment ranged from approximately 3 hours per week in the first week to 5.5 hours per week in the final week due to increased exercise duration and frequency. Subjects were offered a \$50 stipend at the midpoint (after completing baseline testing and the first 5 weeks of the program) and \$50 at the completion of the 10-week intervention and the postintervention tests (total of \$100) to help with transportation and other expenses.

Exercise component—Exercise sessions alternated between aerobic and strengthening programs, at a frequency of 3 to 4 days per week. The exercise intervention was supervised by physical therapists, physical therapy students, or medical students with current cardiopulmonary resuscitation (CPR) certification with a ratio of <5 subjects per supervisor. Blood pressure, heart rate, and blood glucose were monitored before and after exercise. Subjects were not permitted to exercise if resting blood pressure was >160 systolic or 100 diastolic or if blood glucose was <80 or >300. Each exercise session included stretching exercises to warm up and cool down with a 20-second hold and deep breathing during the stretch. The stretches included shoulder shrugs, arm raises, reaching down back, reaching across chest, toe touches, calf stretch, quadriceps stretch, hamstring stretch, and straddle stretch.

The target heart rate for aerobic training was obtained from VO_2 peak values achieved during the baseline graded maximal exercise tests (described in outcomes section). Using these target heart rate values, aerobic exercise was initiated at an intensity of 50% of VO_2 peak for 20 minutes and progressed to a maximum of 70% for 50 minutes. A variety of cardiovascular training equipment was available, including total body recumbent steppers (NuStep, Ann Arbor, Michigan), upright and recumbent cycles, an elliptical cross-trainer, and treadmills (LifeFitness, Schiller Park, Illinois). Participants were encouraged to try out different equipment over the course of the 10-week program, and subjects with absent protective sensation were encouraged to avoid the treadmill. On alternating visits, subjects performed strength training activities (LifeFitness Circuit Series), which included abdominal curl, biceps curl, chest press, lat pulldown, leg extension, seated leg curl, seated row, shoulder press, squat, and triceps press. A baseline 10-repetition maximum weight was established for strength training, and subjects gradually progressed the weight on each exercise to maintain a moderate level of perceived exertion (7-8 on a scale of 0-10).

Nutrition component—A registered dietitian met with the subjects weekly with nutrition sessions modeled after the DPP curriculum, incorporating the recommendations of the diabetes food pyramid with the overall goals of decreasing fat intake and increasing consumption of fruits, vegetables, and whole grains.^{2,10} A binder of informational materials was provided to each subject, and educational games were used to reinforce the information

in a relaxed and fun way. Individualized information was provided to each subject to tailor energy and/or glycemic control goals for specific body weights, and subjects were encouraged to return each week with questions about nutrition or family recipes. Healthy snacks were provided at each session.

Education component—The educational sessions included review of materials from the National Diabetes Educational Program (<http://www.ndep.nih.gov>) relevant to each topic, with emphasis on discussion and application of the information. Family members or other supportive people were invited for all sessions and were specifically included for 2 sessions (“family support day” in week 5, and “graduation ceremony” in week 10).

Outcomes

Glycemic control—Glycosolated hemoglobin (A1C) was assessed with a finger stick blood test using a disposable A1C analyzer (A1CNow+, Bayer Medical Care; Tarrytown, New York). The test gives an indication of the level of glycemic control over a 3-month period. The accuracy of this test is 99% as reported by the manufacturer (95% confidence interval [CI], −1.0% to 0.8%).

Aerobic fitness—A graded maximal exercise test was performed to measure peak oxygen consumption, using an integrated metabolic cart (ParvoMedics TrueOne 2400, Sandy, Utah) with electrocardiography (ECG). A maximal exercise test is indicated for people with diabetes prior to exercise due to the high prevalence of undiagnosed autonomic neuropathy.¹¹ This test was performed in the General Clinical Research Center (GCRC) of the University of Kansas Medical Center. A standard test protocol using a cycle ergometer was performed¹²: subjects began cycling at 50 rpm with 0 W for the first 3 minutes, and the workload was increased by 10 W every minute. Tests were continued until maximal effort was achieved (90% of age-predicted maximal heart rate, respiratory exchange ratio (RER) >1.1, rate of perceived exertion (RPE) >17, and plateau of oxygen consumption in response to increasing workload) or voluntary termination secondary to exhaustion. Two physical therapy students (N.C. and S.B.) blinded to pretest or posttest status evaluated the results of the exercise test post hoc to determine whether maximal effort was achieved. In case of discrepancy, the results were further evaluated by an independent exercise physiologist.

Secondary outcomes—Other measures that were assessed before and after the intervention included the following:

- Body mass index (BMI) (kg/m²).
- Waist:hip ratio: calculated from circumferential measurements at the narrowest part of the torso above the umbilicus and maximal circumference of the buttocks.
- Michigan Neuropathy Screening Instrument (MNSI)¹³: the MNSI has 2 parts: a neuropathic symptom questionnaire completed by subjects (score range, 0-13), and a clinical examination of vibration sensitivity, monofilament sensation, reflexes, and presence of foot ulcers or deformities completed by study personnel (score range, 0-10).
- Pain severity scale¹⁴: using a visual and numeric scale, subjects indicated their pain level on 5 items (average pain, worst pain, frequency of pain, severity of pain, and duration of pain) over the past 4 weeks. A score of 0 indicates “no pain,” and a score of 10 indicates “severe pain.” Scores on individual items are transformed to a 100-point scale and averaged.

- Diabetes Self-Efficacy Scale¹⁵: subjects indicated their level of confidence on a scale of 1 to 10 for 8 items: eat meals including breakfast, follow diet around people without diabetes, choose appropriate foods, exercise regularly, prevent blood glucose drop with exercise, manage blood glucose levels, decide when a doctor visit is necessary, and control diabetes. A score of 1 indicates “not at all confident,” and a score of 10 indicates “totally confident.” The total score is the mean for all items (range, 1-10).
- Grip strength: assessed bilaterally with a hand-grip dynamometer (Jamar, Sammons Preston, Bolingbrook, Illinois).

Data Analysis

Feasibility—Recruitment was assessed by tracking the number of potential subjects assessed for eligibility, as well as those who were excluded because of subject inclusion criteria and those who declined to participate. Information on retention was acquired by tracking the number of subjects who discontinued the intervention during the study along with their reasons. For the subjects who completed the study, adherence was documented as the percentage of total sessions that were attended. We also conducted focus group “exit interviews” at the end of the intervention to gather feedback on recruitment, retention, and adherence issues.

Outcomes—Descriptive statistics of the outcome measures were calculated, and a 2-tailed paired *t* test was used to detect changes before and after the intervention, with significance set at α of .05. The effect size (ES) for the primary outcomes following the intervention was calculated (difference of the means divided by the standard deviation at baseline) to be able to calculate power for a future study.

Results

Feasibility

We assessed 28 potential subjects for eligibility: 11 were enrolled, 11 declined to enroll, and 6 were excluded because of inclusion/exclusion criteria. Of the 11 enrolled subjects, 6 completed the intervention and testing. All 6 subjects who completed the study (mean age, 60.2 ± 4.7 years; mean duration of diabetes, 11 ± 9 years) were white, with 2 males and 4 females. At entry into the study, the mean BMI was 31.4 ± 2.9 ; 2 subjects were overweight (BMI, 25-29.9), and 4 were obese (BMI >30). All 6 subjects had signs of peripheral neuropathy, as demonstrated by MNSI clinical examination scores $>2^{16}$ and mild-moderate ratings of pain severity (range, 15-56 on a 100-point scale) at baseline.

We did not meet our goal of enrolling 20 subjects in the 6-month recruitment period but stopped recruitment because of limited funding and availability of resources. We distributed hundreds of flyers at various clinics and community health fairs, but only 1 of the 11 enrolled subjects was recruited by this method. The other subjects were recruited via university broadcast e-mail ($n = 5$), previous study contacts ($n = 3$), and word of mouth ($n = 2$).

Of the 11 subjects entered into the study, 5 (45%) did not complete the 10-week intervention. One subject had schedule conflicts and did not begin the intervention. We did not receive documentation from physicians for 2 subjects because of concern about liability for undiagnosed medical concerns. To address this, we modified the consent letter to replace a general statement of medical stability with the question “to the best of your knowledge, does your patient have any of these following contraindications to exercise?” followed by a

list of specific conditions. The modified letter was used for the remainder of subjects enrolled in the study.

Two subjects dropped out after beginning the intervention. One developed seasonal asthma after 2 weeks of intervention, and 1 subject developed a new onset of cardiac arrhythmia after 7 weeks of intervention that was detected by our study personnel during the exercise sessions.

The 6 subjects who completed the study attended an average of 95.5% of all scheduled sessions (range, 89%-100%), for 37 total sessions over 10 weeks. Comments during the exit interview were overwhelmingly positive:

“The length of the program was just right: long enough to establish new habits and skills but short enough to fit into my schedule.”

“I’m more energetic, happy, relaxed, and optimistic.”

“Setting goals have helped me in other ways to get more sleep, cutting down caffeine, and watching less TV.”

“This is so far beyond any diabetes classes I’ve ever attended; it would be worth the cost to pay for it out of pocket.”

Outcomes

Mean changes in the primary and secondary outcome measures are presented in Table 2. Improvements in glycosolated hemoglobin or A1C following the intervention approached significance, with an ES of .79. A small, nonsignificant improvement in aerobic fitness (VO₂ peak) was noted after the intervention, with an ES of .36. The majority of graded maximal exercise tests were terminated before maximal effort was achieved, with a range of 2 to 4 of the criteria for maximal effort reached for each test: (1) 90% of age-predicted maximal heart rate, (2) RER >1.1, (3) RPE >17, and (4) oxygen consumption plateau. The mean duration of the exercise tests was 12 minutes and 45 seconds at baseline and 13 minutes and 24 seconds after the intervention.

Conclusions

This systematic approach to analysis of feasibility revealed significant issues with recruitment and retention that would need to be addressed for future studies or if this type of a program were implemented in clinical practice. The recruitment strategies utilized in this study were not adequate for reaching large numbers of potential subjects. Although the subjects who enrolled in this study were overweight and obese with evidence of peripheral neuropathy, neither their ethnic/racial distribution nor glycemic control levels were representative of the general population of people with type 2 diabetes. We were largely unsuccessful in targeting underrepresented populations for this study, and the majority of our subjects were affluent whites who were either retired or currently working at the medical center where the study intervention took place.

A recruitment technique for health promotion that has been suggested is “active marketing,” to directly interact with potential subjects and specifically address their concerns. Reports of successful recruitment strategies in African American communities have recommended presentations with follow-up telephone contacts, the use of an ethnically diverse staff, and partnership with community centers.¹⁷⁻¹⁹ It would be essential to have personnel with Spanish language skills to recruit people of Hispanic ethnicity. Future research should incorporate more aggressive recruitment strategies to connect directly with potential subjects rather than relying on the distribution of flyers and perhaps establish a more formal

academic-community partnership as has been suggested in the literature.²⁰ The use of radio and newspaper advertising could also be explored to target specific markets.

Subject retention was also a concern, with a 25% dropout rate in our study (2 of 8 subjects). This percentage may be inflated by the small number of subjects enrolled, and other studies with similar subjects and interventions have reported dropouts in the range of 0% to 15%.^{6,7} Both subjects who discontinued our program did so because of previously unidentified medical concerns, which is perhaps unavoidable in a population of older adults with type 2 diabetes.

For the subset of subjects who did complete the intervention, adherence was excellent (95.5%) and higher than reported by several other studies (range, 80% -91%).^{6,7} This indicates that the intervention itself was feasible for this subset of subjects, and satisfaction with the program was confirmed by exit interview comments. Further exploration of the complex relationship between the cost and benefit of this intervention as it relates to feasibility may require a qualitative research approach to supplement the quantitative data, as has been suggested to enrich understanding of personal, environmental, and other factors in rehabilitation interventions.²¹

This study did demonstrate medium-large ESs following the intervention in the primary outcomes, although most of the changes were not statistically significant in this small sample. At baseline, subjects had well-controlled blood glucose levels with the mean A1C below the goal of 7% recommended by the American Diabetes Association's clinical practice recommendations.²² If our subjects had started with higher A1C levels, we may have seen a greater effect of the intervention. The change in A1C in our study (-0.5%) is comparable to the value (-0.6%) reported in a meta-analysis of 14 randomized controlled trials of exercise intervention for people with diabetes.²³ One limitation of this outcome measure is that it gives an indication of glycemic control over the previous 3 months, and with a 10-week intervention, the change may actually have been underestimated. Although A1C testing has its limitations, a recent expert consensus confirmed its usefulness in the diagnosis of diabetes and identifying people at risk for complications.²⁴

We did not see statistical improvement in aerobic fitness following this moderately intense, supervised exercise program. However, the graded maximal exercise test may have underestimated aerobic fitness in our subjects. Anticipating that our subjects would be deconditioned at study entry, we selected a conservative test protocol using the cycle ergometer that had been validated for use in subjects with stroke.¹² However, there are several indications that this protocol was not appropriately challenging for our subjects:

- the average duration of the test was longer than the recommended duration of 8 to 12 minutes,²⁵ which may have been due to the prolonged warm-up period (3 minutes at 0 W);
- maximal effort was not achieved in the majority of tests as indicated by standard criteria; and
- the mean aerobic fitness at baseline would put the subjects well below the 10th percentile for healthy subjects over age 60 years.²⁵

For these reasons, we would recommend a cycle exercise protocol with a more aggressive ramping of workload to more accurately measure aerobic fitness.

Our secondary outcome measures showed promising improvements in self-efficacy and pain. With the educational and dietary curriculum emphasis of our intervention, the change in diabetes self-efficacy is not surprising. The improvement in pain does merit further

exploration in future studies, as this may reflect an improvement in neuropathic symptoms or is perhaps a general effect of participating in a healthy lifestyle intervention. There is very little research to guide the clinician on the effect of exercise or health promotion interventions on neuropathic pain or other symptoms.

In summary, subjects in this study did have small improvements in glycemic control, pain, and self-efficacy following this pilot health promotion program. This pilot project enabled us to identify several primary recommendations that will be important to consider for future research or implementing a similar program in clinical practice:

- Recruit subjects through active marketing techniques, including direct personal contacts and community partnerships.
- Use an appropriate exercise test protocol to more accurately assess aerobic fitness.
- Include qualitative research methodology to enhance understanding of health promotion participation and outcomes that may elude standard, quantitative assessment.

Of course, the inclusion of a control group would also be important for comparison, ideally a group that also receives an intervention to minimize the impact of a placebo effect. The results of this pilot study illustrate the need for further study of individualized exercise, dietary counseling, and education for older adults with diabetes.

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Table 1**Summary of Diabetes Health Promotion Program**

Week	Exercise Sessions	Education Session Topic	Nutrition Session Topic
1	2 sessions AE (20 min @ 50% VO ₂ R); 1 session RE (1 set of 10 reps each machine)	Setting goals	Food and Blood Sugar; Self-Monitoring Dietary Intake
2	1 session AE (30 min @ 50% VO ₂ R); 2 sessions RE (1 set of 10 reps each machine)	Monitoring ABCs of diabetes	Diabetes Food Pyramid
3	2 sessions AE (30 min @ 50% VO ₂ R); 1 session RE (1 set of 10 reps each machine)	Healthy and happy feet	Rate Your Plate; Meal Planning
4	2 sessions AE (30 min @ 50% VO ₂ R); 2 sessions RE (1 set of 10 reps each machine)	Risk factors for stroke and CVD	Be a Fat Detective
5	2 sessions AE (30 min @ 60% VO ₂ R); 2 sessions RE (1 set of 10 reps each machine)	Family support day	Be Nutrition Food Label Savvy!
6	2 sessions AE (30 min @ 60% VO ₂ R); 2 sessions RE (1 set of 15 reps each machine)	Stress management	Improve Your Fiber Fitness
7	2 sessions AE (40 min @ 60% VO ₂ R); 2 sessions RE (1 set of 15 reps each machine)	Accessing health information	Tipping the Scale; The Snack Makeover
8	2 sessions AE (40 min @ 60% VO ₂ R); 2 sessions RE (1 set of 15 reps each machine)	Preventing depression	Diabetic Recipes
9	2 sessions AE (40 min @ 70% VO ₂ R); 2 sessions RE (1 set of 15 reps each machine)	Building healthy relationships	Four Keys to Eating Out
10	2 sessions AE (50 min @ 70% VO ₂ R); 2 sessions RE (1 set of 15 reps each machine)	Graduation ceremony	Build a Better Recipe; Review Goals

AE, aerobic exercise; RE, resistance exercise; min, minutes; reps, repetitions; VO₂R, oxygen consumption reserve; CVD, cardiovascular disease.

Table 2

Change in Outcome Measures Following Intervention

	Preintervention	Postintervention	Change	<i>P</i> [*]
A1C, %	6.7 (0.6)	6.2 (0.5)	−0.5 (0.5)	.06
VO ₂ peak, mL/kg/m	15.95 (2.8)	17.0 (2.9)	+0.75 (1.76)	.15
BMI, kg/m ²	31.4 (2.9)	30.5 (3.7)	−0.9 (1.3)	.15
Waist:hip ratio	0.9 (0.08)	0.91 (0.07)	+0.004 (0.3)	.74
MNSI questionnaire	3.5 (3.1)	4.7 (2.2)	+1.2 (1.3)	.08
MNSI clinical examination	3.5 (1.4)	2.7 (2.3)	−0.8 (2.0)	.36
Pain	43.3 (16.1)	30.3 (20.4)	−13 (13)	.06
Self-efficacy	7.4 (1.0)	9.25 (0.7)	1.9 (1.5)	.03 [†]
Grip strength right, kg	30.9 (14.9)	28.5 (11)	−2.4 (4.3)	.23

Presented as mean (standard deviation). A1C, glycosolated hemoglobin level; VO₂ peak, peak oxygen consumption; BMI, body mass index; MNSI, Michigan Neuropathy Screening Instrument.

^{*} *P* value assessed with 2-tailed, paired *t* test.

[†] *P* < .05.